

TCT-123

Transcatheter Aortic Valve Replacement with Edwards Sapien Valve for Treatment of Degenerated Bioprosthesis: UK Sapien User Group Experience

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Background: There has been a progressive increase in the use of bioprostheses for the management of aortic valve disease. Bioprostheses, however, undergo structural degeneration and require replacement in the future especially when implanted in younger age group. Such reoperations carry a high risk especially in elderly patients with multiple comorbidities. Transcatheter aortic valve implantation (TAVI) as a valve-in-valve (V-in-V) procedure may be a reasonable alternative.

Methods: Between February 2009 and February 2011, 31 patients underwent TAVI as a V-in-V using the Edwards Sapien™ valve for the management of failed aortic bioprostheses in United Kingdom. Twenty five had previous stented valves, 3 stentless, and 3 homografts. The youngest patient was 29 years old and the oldest on 91. The mean age was 79.77 ± 7.89 years and 16 (55%) were female. The mean logistic Euroscore was 31.87 ± 10.81 and 92% were in New York Heart Association (NYHA) functional class III-IV. Ten patients presented with predominant stenosis and 21 with regurgitation. Transapical (TA) approach was preferred approach with 26 patients undergoing implant with TA route using Ascendra system and 5 with Transfemoral route using Retroflex or Novoflex delivery system.

Results: Procedural success was achieved in all but 2 patients (93.5%). There were two intra-operative deaths, both due to severe intraoperative regurgitation; one due to torn leaflet while crossing the valve retrograde with earlier version of Retroflex and other due to valve embolisation in a stentless valve due to undersizing. Amongst the survivors there was no 30-day mortality or stroke. There was a significant decrease in mean gradient across the 9 previously stenotic valves from 49.0 ± 21.2 to 11.4 ± 5.2 mmHg (P<0.001). None of the patients had ≥ Grade 1 AR at discharge. One patient required insertion of a permanent pacemaker for persistent AV block. Follow up was complete and all the patients were alive and in NYHA class I-II at a median follow up of 218 days.

Conclusion: The use of TAVI as a V-in-V for the treatment of failed bioprostheses is safe, feasible and offers excellent early results.

TCT-124

Transfemoral Treatment of Bioprosthetic Aortic Valve Failure—Suitability of the Medtronic CoreValve ReValving System

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Background: Reviewing the current literature conventional aortic valve replacement (AVR) for aortic valve stenosis or regurgitation is safe and performed with excellent results. However, a significant number of bioprosthetic valves fail within 15 years, at a time when the patient's risk of redo-surgery has increased. The Medtronic CoreValve ReValving System (MCV) for transfemoral aortic valve implantation (TAVI) represents an alternative. Therefore, the aim of the study was to elucidate whether TAVI in patients (pts) with a failing aortic bioprosthesis is safe and feasible.

Methods: Pts with symptomatic aortic valve disease and higher surgical risk were enrolled. MCV implantation was performed using the transfemoral approach under local anesthesia. Clinical events were recorded and echocardiography was performed to evaluate hemodynamics at follow-up.

Results: A total of 26pts (age 78±7years) with a logEuroSCORE of 33±17.6% were treated so far. The duration between conventional AVR and MCV implantation was 56±44months, the inner diameter of the bioprosthesis was 21.7±2.3mm. Twenty pts received the TAVI for treatment of a stenotic bioprosthetic valve, whereas five were treated because of severe aortic regurgitation. The MCV prosthesis was successfully implanted in all patients. In those with stenosis, the mean gradient declined from 46±16mmHg to 12±7mmHg after MCV (p<0.05), in those with AR the level declined by 10%. Additionally the fraction of pts with NYHA class III/IV decrease from 75% to 15% and was stable through out a mean follow-up of 410±183days. There was no intraprocedural death, one patient died from a severe stroke and one patient from cardiac failure within 24h after TAVI. There was one further death during the one-year follow-up period (30day-mortality:7.7%). Applying the VARC criteria device success was achieved in 22pts (85%). Freedom from the combined safety endpoint was detected in 20pts (79%).

Conclusion: These results suggest that TAVI into a failing aortic bioprosthetic and the use of the MCV is feasible, safe and improves hemodynamics in high risk patients.

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Transcatheter Aortic-Valve Implantation for the Treatment of Degenerative Bioprosthetic Surgical Valves: Results from the Global VIV (Valve-in-Valve) Registry

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Background: Transcatheter aortic valve-in-valve (VIV) implantation is an emerging therapeutic alternative for patients with failed surgical bioprosthetic valves. This technique might obviate the need for a redo surgical procedure. The clinical experience with VIV implantation is still limited, and it is currently considered an off-label treatment. We present the procedural and clinical results from a large worldwide retrospective VIV Registry.

Methods: Data on baseline patient characteristics, procedural parameters, and outcome up to June 2011 were collected from 35 cardiac centers that have performed VIV procedures using a uniform case-report form.

Results: In total, 159 VIV procedures were performed (1 to 25 procedures per center, median 3); men 50.9%; ages ranged from 25 to 91 years (mean, 77.4±10.5 years). The prevalence of severe co-morbidities was very high: the mean calculated logistic EuroSCORE was 30.6±17.4% and the Society of Thoracic Surgeons (STS) risk score, 12.5±11.8%. Patients had had up to 4 previous surgeries; one previous surgery in 81% of cases. The main mode of bioprosthesis failure was stenosis (n=75, 47.2%), followed by regurgitation (n=64, 40.3%) and combined stenosis and regurgitation (n=20, 12.6%). The mean aortic-valve area measured 0.98±0.55 mm², and the valve gradients (max/mean), 66.5±30.9/38.9±19.8 mmHg. Mean left ventricular ejection fraction was 49.6±13.2%. One-hundred and two procedures (64.2%) were performed using the CoreValve device and 57 (35.8%) using the Edwards-SAPIEN valve. Femoral access was used in 109 cases (68.6%), apical in 38 (23.9%), axillary in 10 (6.3%), and direct-aortic in 2 (1.3%). Implantation was successful in 96.9% of cases, which showed a mean decrease in valve gradients to 27.5±13.6/15.8±8.6 mmHg. Adverse outcomes consisted of significant aortic regurgitation (≥2) in 6.9% of cases, need for pacemaker implantation in 8.7%, and major stroke in 2.1%. The median duration of hospital stay was 8 days. The 30-day total death rate was 8.6%, and the cardiac mortality rate was 6.1%.

Conclusion: Analysis of the retrospective global registry data indicates that the transcatheter VIV procedure is feasible and relatively safe in very high risk patients with failed surgical bioprosthetic valves.

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Transcatheter Valve-in-Valve Implantation for Failed Balloon Expandable Transcatheter Aortic Valves

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Background: Device malposition after transcatheter aortic valve replacement can cause significant clinical and hemodynamic instability. Aortic regurgitation following transcatheter heart valve (THV) implantation may be valvular due to prosthetic leaflet dysfunction or paravalvular due to poor annular sealing. When regurgitation is severe implantation of a second valve (THV-in-THV) may be effective by restoring normal leaflet function or extending the annular seal.

Methods: Patients undergoing aortic balloon-expandable THV-in-THV implantation at 3 centres (St. Paul's Hospital, Vancouver, the Quebec Heart and Lung Institute, Quebec, and the Cleveland Clinic, Cleveland) were studied.

Results: A total of 19 patients (age 80 ± 8 years, 53% male) were analyzed. Aortic regurgitation after the first implanted valve was paravalvular in 14 patients (implant too high in 2 patients, too low in 10 patients, and angiographically correct positioning in 2 patients) and transvalvular in 5 patients (4 Edwards SAPIEN valves, 1 Cribier Edwards valve). THV-in-THV implantation was successful in 17/19 (89%), while 2 patients (11%) required conversion to open heart surgery (the second valve embolized in both cases, 1 patient died in hospital). None of the patients had transvalvular aortic regurgitation after the second procedure. In those 17 patients who underwent a successful THV-in-THV implantation, paravalvular aortic regurgitation was none in 4, mild in 11 and moderate to severe in 2 patients. Mean aortic valve gradient fell from 36 ± 11 mmHg to 13 ± 5 mmHg (p < 0.001) after implantation of the second valve.